ABBOTT PRISM HCV
Hepatitis C Virus Encoded Antigens
(Recombinant c100-3, HCr43, NS5)

Customer Service
For additional product information, please contact your local customer service organization.

NOTE: This package insert must be read carefully prior to product use. Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

NOTE: If you receive reagents, calibrators, controls or bulk solutions that are in a condition contrary to the package insert or label recommendation, or that are damaged, contact your local customer service organization.

For use with software version 2.1 or higher

Key to symbols used

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>List Number</td>
</tr>
<tr>
<td>IVD</td>
<td>In Vitro Diagnostic Medical Device</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot Number</td>
</tr>
<tr>
<td>•</td>
<td>Expiration Date</td>
</tr>
<tr>
<td>2°C</td>
<td>Store at 2-8°C</td>
</tr>
<tr>
<td>15°C</td>
<td>Store at 15-30°C</td>
</tr>
<tr>
<td>⚠️</td>
<td>CAUTION: Consult accompanying documents.</td>
</tr>
<tr>
<td>🏛️</td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>

See REAGENTS section for a full explanation of symbols used in reagent component naming.
THE ABBOTT PRISM HCV ASSAY

NAME AND INTENDED USE

The ABBOTT PRISM HCV assay is an in vitro chemiluminescent immunoassay (ChLIA) for the qualitative detection of antibodies to hepatitis C virus (anti-HCV) in human serum or plasma. The ABBOTT PRISM HCV ChLIA is intended as a screen for donated blood to prevent transmission of hepatitis C virus (HCV) to recipients of blood and blood components and as an aid in the diagnosis of hepatitis C viral infection.

SUMMARY AND EXPLANATION OF THE TEST

Serological studies to detect the antibodies to recombinant antigens of HCV have established HCV as the cause of most blood-borne, 1,6 as well as community acquired, 7 non-A, non-B hepatitis (NANBH). Thus, the presence of anti-HCV indicates that an individual may have been infected with HCV, may harbor infectious HCV and may be capable of transmitting HCV infection. 8 However, as with all immunoassays, the ABBOTT PRISM HCV assay may yield non-specific reactivity due to other causes, particularly when testing low prevalence populations. Although the majority of infected individuals may be asymptomatic, complications of HCV infection may include chronic hepatitis, cirrhosis and increased risk of hepatocellular carcinoma. 9,12 The implementation of blood donor screening for anti-HCV has led to a marked decline in the risk of transfusion-transmitted hepatitis. 13,14

The ABBOTT PRISM HCV assay is intended as a screen for donated blood to prevent hepatitis C virus (anti-HCV) in human serum or plasma. The ABBOTT PRISM HCV assay is a two-step sandwich ChLIA that detects antibodies to hepatitis C virus in human serum or plasma. The reactions occur in the following sequence:

• Microparticles coated with HCV recombinant antigens are incubated with Specimen Diluent and either plasma, serum, calibrator or control in the incubation well of the reaction tray. During incubation, HCV antibodies present in the sample bind to the antigen(s) on the microparticles.

• After this first incubation is complete, the reaction mixture is transferred to the glass fiber matrix (matrix) of the reaction tray using the Transfer Wash. The microparticles are captured by the matrix while the remaining mixture flows through to the absorbent blotter.

• The anti-biotin (mouse monoclonal): acridinium conjugate/biotinylated F(ab')2 fragment (goat) anti-human IgG is added to the microparticles on the matrix and incubated. After this second incubation, the unbound conjugate is washed into the blotter with the Conjugate Wash.

• The chemiluminescent signal is generated by addition of an alkaline hydrogen peroxide solution. The resultant photons are counted. The amount of light emitted is proportional to the amount of antibody to HCV in the sample. For further information regarding ChLIA technology, refer to the ABBOTT PRISM Operations Manual, Section 3. The presence or absence of antibody to HCV in the sample is determined by comparing the number of photons collected from the sample to a cutoff value determined from an ABBOTT PRISM calibration performed in the same batch. If the number of photons collected from a test sample is greater than or equal to the cutoff value, the sample is considered reactive for antibody to HCV. Specimens which are not reactive by the ABBOTT PRISM HCV assay are considered nonreactive for antibody to HCV. These specimens need not be further tested. Specimens which are initially reactive should be centrifuged according to the table in the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS section and retested in duplicate.

REAGENTS

NOTE: Each specific component description noted below is accompanied by a unique symbol. These symbols appear on both the component labels and on corresponding instrument tubing identifier labels. They are meant to facilitate identification and installation of reagent bottles within the ambient reagent bay and refrigerator.

ABBOTT PRISM HCV Assay Kit (6A52-48)

• [MICROPARTICLES] 1 bottle (325 mL) hepatitis C virus encoded antigens (recombinant c100-3, HCr43, NS5) coated microparticles in phosphate buffered saline. Preservative: sodium azide. (Symbol: □)

• [CONJUGATE] 1 bottle (332 mL) anti-biotin (mouse monoclonal): acridinium conjugate/biotinylated F(ab')2 fragment (goat) anti-human IgG (gamma) in phosphate buffer, bovine serum albumin and Triton X-100. Preservative: sodium azide. (Symbol: ▪)

Specifications:

The ABBOTT PRISM HCV assay is a two-step sandwich ChLIA that detects antibodies to hepatitis C virus in human serum or plasma. The reactions occur in the following sequence:

1. Microparticles coated with HCV recombinant antigens are incubated with Specimen Diluent and either plasma, serum, calibrator or control in the incubation well of the reaction tray. During incubation, HCV antibodies present in the sample bind to the antigen(s) on the microparticles.

2. After this first incubation is complete, the reaction mixture is transferred to the glass fiber matrix (matrix) of the reaction tray using the Transfer Wash. The microparticles are captured by the matrix while the remaining mixture flows through to the absorbent blotter.

3. The anti-biotin (mouse monoclonal): acridinium conjugate/biotinylated F(ab')2 fragment (goat) anti-human IgG is added to the microparticles on the matrix and incubated. After this second incubation, the unbound conjugate is washed into the blotter with the Conjugate Wash.

4. The chemiluminescent signal is generated by addition of an alkaline hydrogen peroxide solution. The resultant photons are counted. The amount of light emitted is proportional to the amount of antibody to HCV in the sample. For further information regarding ChLIA technology, refer to the ABBOTT PRISM Operations Manual, Section 3. The presence or absence of antibody to HCV in the sample is determined by comparing the number of photons collected from the sample to a cutoff value determined from an ABBOTT PRISM calibration performed in the same batch. If the number of photons collected from a test sample is greater than or equal to the cutoff value, the sample is considered reactive for antibody to HCV. Specimens which are not reactive by the ABBOTT PRISM HCV assay are considered nonreactive for antibody to HCV. These specimens need not be further tested. Specimens which are initially reactive should be centrifuged according to the table in the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS section and retested in duplicate.

The Recombinant HCV Proteins in ABBOTT PRISM HCV

<table>
<thead>
<tr>
<th>HCr43</th>
<th>NS5</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV AA #1-150 + 1192-1457</td>
<td>HCV AA #2054-2995</td>
</tr>
<tr>
<td>C</td>
<td>F1</td>
</tr>
<tr>
<td>E1</td>
<td>E2</td>
</tr>
<tr>
<td>NS2</td>
<td>NS3</td>
</tr>
<tr>
<td>c100-3</td>
<td>HCV AA #1569-1931</td>
</tr>
<tr>
<td>HCV Polyprotein AA #1-3011</td>
<td></td>
</tr>
</tbody>
</table>
- **CAUTION**: This product contains human sourced infectious and/or potentially infectious components. Refer to the REAGENTS section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, it is recommended that all human sourced materials be considered potentially infectious and handled with appropriate biosafety practices.

**Safety Precautions**

- The ABBOTT PRISM Activator Diluent contains sodium hydroxide and is classified per the applicable European Community (EC) Directives as: Irritant (X). The following are the appropriate Risk (R) and Safety (S) phrases.

- **R36** Irritating to eyes.
- **S26** In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- **S35** This material and its container must be disposed of in a safe way.
- **S46** If swallowed, seek medical advice immediately and show this container or label.

This product contains sodium azide; some reagents contain sodium hydroxide. For a specific listing, refer to the REAGENTS section. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way. For product not classified as dangerous per European Directive 1999/45/EC as amended - Safety data sheet available for professional user on request.

**Handling Precautions**

- **CAUTION**: If the ABBOTT PRISM HCV assay is selected, put on clean gloves before handling HCV conjugate. HCV conjugate is neutralized by contamination with human IgG. Extreme caution must be exercised when handling all containers, tubing, and accessories which may come in contact with the conjugate.
- Do not use kits beyond the expiration date.
- Gently invert each component several times prior to loading on the ABBOTT PRISM System to ensure a homogenous solution. Avoid foaming. Each component of the ABBOTT PRISM HCV Wash Kit should be at room temperature (15 to 30°C) before mixing.
- Do not mix reagents from different bottles. Do not mix reagents from different assay kit lots.
- Any lot of ABBOTT PRISM HCV Wash Kit can be used with any lot of ABBOTT PRISM HCV Assay Kit.
- Avoid microbial and chemical contamination of samples, reagents, and equipment. The use of disposable pipette tips is recommended for any preliminary sample transfer.
- Do not freeze reagents.
- Failure to adhere to instructions in the ABBOTT PRISM Operations Manual or Package Insert may result in erroneous results.
- Use caution when handling samples, reagent bottles, and reagent accessories which may come in contact with the conjugate.

Additional safety and handling precautions and limitations for the assay kit, calibrators, specimens, controls, and other reagents are described in the ABBOTT PRISM Operations Manual, Section 7.

**PREPARATION OF ACTIVATOR SOLUTION**

Activator Solution is prepared daily by mixing equal parts of Activator Concentrate and Activator Diluent. The volume of Activator Solution required for multiple tests is calculated by the ABBOTT PRISM software. Refer to the ABBOTT PRISM Operations Manual, Section 5, under Plan Work Load, for additional information. Use clean pipettes and/or metal-free containers (such as plasticware or acid-washed and distilled or deionized water-rinsed glassware) to measure. Prepare in the bottle provided in the Accessory Kit. Cover the bottle opening securely with the cap provided and invert gently five to ten times to mix. Load the Activator Solution on the PRISM System. Refer to the ABBOTT PRISM Operations Manual, Section 5, under Prepare and Load Activator Solution, for additional information.

**NOTE:** The Activator Solution must be used within 24 hours of preparation.
STORAGE INSTRUCTIONS

- Store the ABBOTT PRISM HCV Assay Kit, ABBOTT PRISM Run Control Kit, ABBOTT PRISM Positive Run Control Kit, and ABBOTT PRISM Activator Concentrate at 2 to 8°C.
- Store the ABBOTT PRISM HCV Wash Kit and ABBOTT PRISM Activator Diluent at room temperature (15 to 30°C).
- Store ABBOTT PRISM Pipette Tips and ABBOTT PRISM Reaction Trays in their original package until use.

INDICATIONS OF INSTABILITY OR DETERIORATION OF REAGENTS

The ABBOTT PRISM System will not continue to process samples when calibrator values do not meet specifications. This may indicate either deterioration or contamination of reagents, or instrument failure. Refer to the ABBOTT PRISM Operations Manual, Section 10, for additional information.

INSTRUMENT PROCEDURE

- Refer to the ABBOTT PRISM Operations Manual for a detailed description of Instrument Procedures.
- Solutions required for instrument cleaning and maintenance are described in detail in the ABBOTT PRISM Operations Manual, Sections 5 and 9.
- For optimal performance, it is important to follow the routine maintenance procedures defined in the ABBOTT PRISM Operations Manual, Section 9.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

- Either serum (including serum collected in serum separator tubes) or plasma collected in EDTA, Potassium Oxalate, Sodium Citrate, ACD, CP2D, CPD, or CPDA-1 anticoagulants may be used with the ABBOTT PRISM HCV assay.
- Heat-inactivated specimens should be avoided.
- Gravity separation is not sufficient for specimen preparation. Specimens collected by plasmapheresis which have not been frozen do not require centrifugation. All other specimens (including previously frozen plasmapheresis specimens) must be centrifuged.
- Non-frozen specimens (excluding non-frozen plasmapheresis specimens) must be centrifuged such that g-minutes (the product of relative centrifugal force [RCF] and centrifugation time [minutes]) is between 30,000 and 75,000. The following chart lists acceptable time and force ranges that meet this criteria.

<table>
<thead>
<tr>
<th>Time (minutes)</th>
<th>RCF (x g)</th>
<th>RCF x Time (g-minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>3,000</td>
<td>30,000</td>
</tr>
<tr>
<td>15</td>
<td>2,000 - 3,000</td>
<td>30,000 - 45,000</td>
</tr>
<tr>
<td>20</td>
<td>1,500 - 3,000</td>
<td>30,000 - 60,000</td>
</tr>
<tr>
<td>25</td>
<td>1,300 - 3,000</td>
<td>32,500 - 75,000</td>
</tr>
</tbody>
</table>

Convert rpm to RCF as follows: RCF = \( 1.12 \times r_{\text{max}} \) \( \text{rpm}/1000 \)^2

Convert RCF to rpm as follows: \( \text{rpm} = 1000 \times \sqrt{\frac{\text{RCF}}{1.12 \times r_{\text{max}}}} \)

NOTE: Do not use specimens collected in heparin. Use of heparin as an anticoagulant may cause a reduction in Sample Net Counts or plasma from individual donor specimens. Pooled specimens must not be used.

This assay was designed and validated for use with human serum or plasma from individual donor specimens. Pooled specimens must not be used.

Heat-inactivated specimens should be avoided.

Gravity separation is not sufficient for specimen preparation. Specimens collected by plasmapheresis which have not been frozen do not require centrifugation. All other specimens (including previously frozen plasmapheresis specimens) must be centrifuged.

Non-frozen specimens (excluding non-frozen plasmapheresis specimens) must be centrifuged such that g-minutes (the product of relative centrifugal force [RCF] and centrifugation time [minutes]) is between 30,000 and 75,000. The following chart lists acceptable time and force ranges that meet this criteria.

<table>
<thead>
<tr>
<th>Time (minutes)</th>
<th>RCF (x g)</th>
<th>RCF x Time (g-minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>12,000</td>
<td>180,000</td>
</tr>
<tr>
<td>20</td>
<td>9,000 - 12,000</td>
<td>180,000 - 240,000</td>
</tr>
<tr>
<td>25</td>
<td>7,200 - 12,000</td>
<td>180,000 - 300,000</td>
</tr>
</tbody>
</table>

ANY specimen (excluding non-frozen plasmapheresis) not tested within 24 hours of initial centrifugation must be re-centrifuged from 30,000 to 75,000 (g-minutes) as defined for non-frozen specimens.

**SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS**

- Clear, non-hemolyzed specimens should be used when possible. Specimens containing particulate matter may give erroneous or inconsistent results.
- No qualitative performance differences were observed when nonreactive and low-level reactive specimens were spiked with elevated levels of bilirubin (≤ 20 mg/dL), hemoglobin (≤ 500 mg/dL), or lipids (≤ 3000 mg/dL).
- When shipped, specimens must be packaged and labeled in compliance with applicable regulations covering the transport of clinical specimens and etiologic agents. Specimens may be shipped under ambient conditions, refrigerated on wet ice (2 to 8°C), or frozen on dry ice (-10°C or colder). Prior to freezing, the specimen should be removed from the clot or red cells.
- Performance has not been established for cadaver specimens, umbilical cord blood, or body fluids such as urine, saliva, semen, amniotic fluid, cerebrospinal fluid, or pleural fluid.
Specimen Volume

The specimen volume required to perform a single assay on the ABBOTT PRISM System varies according to the different specimen containers. For ABBOTT PRISM Sample Cups, the minimum specimen volume required for one assay is 350 μL. The ABBOTT PRISM HCV Assay requires 50 μL sample dispense.

For volume requirements for each additional assay performed from the same specimen container and for volume requirements in primary or aliquot tubes, refer to the ABBOTT PRISM Operations Manual, Section 5.

ABBOTT PRISM HCV PROCEDURE

Materials Provided
- 6A52-48 ABBOTT PRISM HCV Assay Kit*
- 6A52-38 ABBOTT PRISM HCV Wash Kit

Materials Required but not Provided
- 1A75-02 or 3L27-02 ABBOTT PRISM ACTIVATOR CONCENTRATE
- 1A75-01 or 3L27-01 ABBOTT PRISM ACTIVATOR DILUENT
- 5A07-01 ABBOTT PRISM REACTION TRAYS
- 5A07-10 ABBOTT PRISM PIPETTE TIPS
- 6A36-60 ABBOTT PRISM Accessory Kit

Additional Materials Available
- 1A75-10 or 3L27-10 ABBOTT PRISM ACTIVATOR LINE TREATMENT
- 2K24-10 ABBOTT PRISM Run Control Kit
- 2K24-11 ABBOTT PRISM Positive Run Control Kit
- 5E22-10 ABBOTT PRISM Run Control Kit
- 5E22-11 ABBOTT PRISM Positive Run Control Kit
- 6A36-31 ABBOTT PRISM RUN CONTROL ADAPTERS
- 7A03-01 or 3L00-01 ABBOTT PRISM PRIME/PURGE ACCESSORIES
- 7A03-30 or 3L00-30 ABBOTT PRISM PURGE CONCENTRATE
- 7A03-31 ABBOTT PRISM LINE CLEANER
- 7B36-01 ABBOTT PRISM SAMPLE CUPS

ABBOTT PRISM ASSAY PROCEDURE

For detailed information concerning batch time and maximum batch size, refer to the ABBOTT PRISM Operations Manual, Section 2.

STEP 1:
- Enter a Plan Work Load (refer to ABBOTT PRISM Operations Manual, Section 5).
- Replace reagents as needed.

NOTE: Gently invert each component several times prior to loading on the ABBOTT PRISM System to ensure a homogenous solution. Additional gentle inversion may be required to thoroughly resuspend microparticles. Avoid foaming. Each component of the ABBOTT PRISM HCV Wash Kit should be at room temperature (15 to 30°C) before mixing.

- Verify that all tubing label symbols match the symbols on each reagent label. (Refer to the symbol key in the PREPARATION OF ACTIVATOR SOLUTION section of this package insert) and load into the ABBOTT PRISM System.

STEP 2:
- Inspect the waste containers. Empty and clean as defined in the ABBOTT PRISM Operations Manual, Section 9, if necessary.

STEP 3:
- Prepare Activator Solution (refer to the PREPARATION OF ACTIVATOR SOLUTION section of this package insert) and load into the ABBOTT PRISM System.

* Average expected kit utilization is 4100 tests per kit. Actual utilization will vary by customer.
3. Customer-Specified Control Handling Procedure
   a. Determine the volume of controls required. The control volume required to perform a single assay on the ABBOTT PRISM System varies according to the different specimen containers. For ABBOTT PRISM Sample Cups, the minimum control volume required for one assay is 500 μL (300 μL + 200 μL Sample Cup dead volume). For every additional assay performed from the same control container, an additional 100 μL is required. For volume requirements in primary or aliquot tubes, refer to the ABBOTT PRISM Operations Manual, Section 5.
   b. Refer to the ABBOTT PRISM Operations Manual, Section 5: Operating Instructions, Subsection: Sample Processing.

4. Additional controls may be run at the operator’s discretion. Validity specifications may be assigned such that if these controls fail, no results are reported for that assay batch.

ASSAY PARAMETER SPECIFICATIONS
The PRISM assay parameter specifications have been factory set. These parameters cannot be printed, displayed, or edited.

RESULTS
Calculation of Cutoff and S/CO Values
The ABBOTT PRISM System calculates the ABBOTT PRISM HCV assay cutoff value using the following formula:

\[
\text{Cutoff} = \frac{\text{Mean Negative Calibrator Net Counts} + (0.55 \times \text{Mean Positive Calibrator Net Counts})}{1}
\]

Example: If the Mean NCC = 2,500, and the Mean PCC = 30,000,
\[
\text{Cutoff} = \frac{2,500 + (0.55 \times 30,000)}{1} = 19,000
\]

\* The Mean Positive Calibrator and Negative Calibrator Net Counts are calculated using the two lowest replicates. An instrument code (02-211) will be displayed in place of the count value for the third replicate. Each of the two remaining replicates of the Positive Calibrator and the Negative Calibrator used to calculate the cutoff must meet all specifications.

The ABBOTT PRISM System calculates the ABBOTT PRISM HCV assay S/CO using the following formula:

\[
\text{S/CO} = \frac{\text{Sample Net Counts}}{\text{Cutoff}}
\]

Example: If the Sample Net Counts = 32,000, and the Cutoff = 19,000,
\[
\text{S/CO} = \frac{32,000}{19,000} = 1.68
\]

INTERPRETATION OF RESULTS
In the ABBOTT PRISM HCV assay, specimens with Net Counts less than the cutoff are considered nonreactive and need not be further tested. Specimens with Net Counts greater than or equal to the cutoff are considered reactive. All specimens that are reactive on initial testing must be centrifuged according to the table in the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS of this package insert and retested in duplicate.

NOTE: If re-testing a specimen within 24 hours of the initial centrifugation, the specimen is not required to be re-centrifuged. If repeat testing shows the Net Counts for both retests to be less than the cutoff, the sample is considered nonreactive. If either duplicate retest Net Count is greater than or equal to the cutoff, the specimen is repeatedly reactive. Repeatedly reactive specimens should be investigated further in supplemental tests such as other HCV specific immunoassays and immunoblot assays or a combination thereof.

AaBBOTT PRISM reports display sample results in Net Counts and/or S/CO. Net Counts are used by ABBOTT PRISM to interpret results. The S/CO value is provided in reports to show relative reactivity to the cutoff. In the ABBOTT PRISM HCV assay, specimens with S/CO values of less than 1.00 are considered nonreactive. Specimens with an S/CO value of greater than or equal to 1.00 are considered reactive.

For details on configuring the ABBOTT PRISM System to use Grayzone Interpretations, refer to the ABBOTT PRISM Operations Manual, Section 2.

READING RESULTS
Some S/CO values may be flagged with "<" or ">" symbols. Refer to the ABBOTT PRISM Operations Manual, Section 5: Operating Instructions, Subsection: Reports.

SYSTEM ERRORS
For a description of the error codes that appear in the ABBOTT PRISM Report, refer to the ABBOTT PRISM Operations Manual, Section 10.

LIMITATIONS OF THE PROCEDURE
- Testing of previously frozen samples with the ABBOTT PRISM HCV assay may cause erroneous results.
- This assay was designed and validated for use with human serum or plasma from individual patient and donor specimens. Pooled specimens must not be used since the accuracy of their test results has not been validated.
- It is recommended that repeatedly reactive specimens be investigated by supplemental testing. Individuals who are repeatedly reactive may be referred for medical evaluation which may include additional testing.
- False reactive results can be expected with any test kit. Falsely elevated results have been observed due to non-specific interactions (see Table II).
- Performance has not been established for body fluids other than serum or plasma.
- Previously frozen specimens must be centrifuged per the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS section of this package insert prior to running the assay.
- Serum from heparinized patients may be incompletely coagulated. Erroneous or inconsistent results may occur due to the presence of fibrin. To prevent this phenomenon, draw specimen prior to heparin therapy.
- Do not use specimens collected in heparin. Use of heparin as an anticoagulant may cause a reduction in Sample Net Counts and in S/CO (Sample Net Counts/Cutoff).
- The use of specimens with obvious microbial contamination should be avoided.
- Although the association of infectivity and the presence of anti-HCV is strong, it is recognized that presently available methods for anti-HCV detection are not sensitive enough to detect all potentially infectious units of blood or possible cases of HCV infection.

EXPECTED RESULTS
In a random population of 6,742 volunteer blood donor specimens, 26 (0.39%) were reactive by ABBOTT PRISM HCV. Among 419 specimens from individuals with acute or chronic HCV infection and preselected anti-HCV positive specimens, the ABBOTT PRISM HCV assay detected 100.00% as repeatedly reactive.

SPECIFIC PERFORMANCE CHARACTERISTICS
NOTE: Representative performance data are shown. Results obtained at individual laboratories may vary.

Precision
Assay reproducibility was determined by assaying a 16 member panel consisting of four replicates each of three diluted specimens reactive for anti-HCV (panel members 1, 2, and 3) and one specimen nonreactive for anti-HCV (panel member 4). The panel was tested in five runs over five days with each of three master lots at a total of three sites. The intra- and inter-assay standard deviation (SD) and percent coefficient of variation (%CV) were analyzed with a variance components analysis, using a nested analysis of variance model19 (Table I).

Mean S/CO is defined as the mean Sample Net Counts (NET) divided by the calculated Cutoff.
Patients Random Hospital

Infection and Unrelated to HCV Medical Conditions

<table>
<thead>
<tr>
<th>GROUP/TYPE</th>
<th>n (%)</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasma</td>
<td>306</td>
<td>306</td>
</tr>
<tr>
<td>Serum</td>
<td>306</td>
<td>306</td>
</tr>
</tbody>
</table>

Specificty

The specificity of the ABBOTT PRISM HCV assay was estimated assuming a zero prevalence of HCV in volunteer blood donors and plasmapheresis donors.

A total of 6,742 serum and plasma specimens from volunteer blood donors and plasmapheresis donors was collected from four blood centers (Table II). Of the 26 repeatedly reactive specimens eight were excluded as confirmed positive by ABBOTT MATRIX HCV 2.0 and/or RIBA 2.0. Therefore, of the 6,734 donations presumed seronegative for anti-HCV, ABBOTT PRISM HCV had an estimated specificity of 99.73% (6,716/6,734).

Specimens from individuals with medical conditions unrelated to HCV infection or containing potentially interfering substances and specimens from random hospital patients were tested with the ABBOTT PRISM HCV assay (Table II).

<table>
<thead>
<tr>
<th>TABLE II</th>
<th>Reactivity in Donor Populations, in Random Hospital Patients, and in Specimens from Individuals with Medical Conditions Unrelated to HCV Infection or Containing Potentially Interfering Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group/Type</td>
<td>Number of Specimens Tested</td>
</tr>
<tr>
<td>-----------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>Volunteer Blood Serum Donors</td>
<td>3,060</td>
</tr>
<tr>
<td>Donors Plasmapheresis Donors</td>
<td>3,179</td>
</tr>
<tr>
<td>TOTAL DONORS</td>
<td>6,742</td>
</tr>
<tr>
<td>Random Hospital Patients</td>
<td>303</td>
</tr>
<tr>
<td>Medical Conditions Unrelated to HCV Infection and Potentially Interfering Substances</td>
<td>306</td>
</tr>
</tbody>
</table>

Detectability

Specimens obtained from patients with acute and chronic HCV infections, preselected anti-HCV positive specimens, and populations at increased risk of HCV infection were tested with the ABBOTT PRISM HCV assay. The ABBOTT PRISM HCV assay detected all of the 496 confirmed positive specimens (100.00%) (Table III).
BIBLIOGRAPHY


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